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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,902	06/26/2003	Jeffrey Sutton	DEP5114	7208

27777 7590 01/13/2005
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EXAMINER

STRAIGHTIFF, MICHAEL PAUL

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,902

Applicant(s)

SUTTON, JEFFREY

Examiner

Michael P. Straighttiff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,11-20,71 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,11-20,71 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species I (Figures 1, 2A, and 2B) dated 12/06/2004 is acknowledged. Applicant's election denotes Claims 5, 11-20, and 75 as the related claims. Claims 1 and 71 will be examined as claims generic to the elected species.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 11-14, 17, and 18 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,762,130 to Fogarty.
 - a. In regard to Claim 1, Fogarty discloses "[A] therapeutic probe, comprising: a proximal end portion, a distal end portion, a longitudinal portion" (See Fogarty, Figure 1), a "therapeutic agent-delivering means provided in the longitudinal portion" (See Fogarty, Figure 8, Reference 38; See also Column 1, Lines 62-66), "wherein the back side surface of the longitudinal portion is adapted to conform to a contour of the adjacent tissue" (See Fogarty, Column 3, Lines 24-27, particular reference to "flexible").

- b. In regard to Claim 5, Fogarty further discloses "wherein the back side surface comprises a helical shape" (See Fogarty, Figures 1 and 8; See also Column 1, Lines 9-11).
- c. In regard to Claim 11, Fogarty discloses "[A] therapeutic probe, comprising: a proximal end portion, a distal end portion, a longitudinal portion located between the proximal and distal portions" (See Fogarty, Figure 1), a "therapeutic-agent delivering means provided in the longitudinal portion" (See Fogarty, Figure 8, Reference 38; See also Column 1, Lines 62-66), and "wherein the outer surface of the longitudinal portion comprises a threadform" (See Fogarty, Figures 1 and 8; See also Column 1, Lines 9-11).
- d. In regard to Claim 12, Fogarty further discloses "wherein the threadform comprises an expandable device" (See Fogarty, Figures 1 and 8; See also Column 1, Lines 9-11).
- e. In regard to Claim 13, Fogarty further discloses "wherein the expandable device is adapted to conform to a contour of the adjacent tissue". The examiner concludes that conformability is inherent in the nature of an inflatable threadform balloon.
- f. In regard to Claim 14, Fogarty further discloses "wherein the expandable device comprises a balloon" (See Fogarty, Figures 1 and 8; See also Column 1, Lines 9-11).
- g. In regard to Claim 17, Fogarty further discloses "the proximal end portion comprises a first expandable portion" (See Fogarty, Figures 1 and 8). The

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intended use/functional language "adapted to conform" carries limited patentable weight in the absence of any distinguishing structural feature.

h. In regard to Claim 18, Fogarty further discloses "the distal end portion comprises a second expandable portion" (See Fogarty, Figures 1 and 8). The intended use/functional language "adapted to conform" carries limited patentable weight in the absence of any distinguishing structural feature.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,762,130 to Fogarty as applied to Claim 11 above and in further view of U.S. Patent No. 5,411,509 to Hilal.

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a. In regard to Claims 15 and 16, Fogarty discloses "[A] therapeutic probe" (See Claim 11 Rejection). Fogarty does not meet the limitations "wherein the threadform comprises a malleable portion" of Claim 15 or "wherein the malleable portion comprises a foam portion" of Claim 16. Hilal teaches a foam portion on the distal tip of an embolectomy catheter (See Hilal, Column 2, Lines 63-67; See also Column 4, Lines 1-3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a malleable, foam material as taught by Hilal as the threadform on the device disclosed by Fogarty in order to provide a threadform that will not overinflate or puncture.

6. Claims 19-20, 71, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,762,130 to Fogarty in view of U.S. Patent No. 5,944,687 to Benett et al.

a. In regard to Claims 19 and 20, Fogarty discloses "[A] therapeutic probe" (See Claim 11 Rejection). Fogarty does not explicitly meet the limitations "wherein the therapeutic agent delivering means comprises an energy delivery device" of Claim 19 or "wherein the energy-delivering means is an ultrasound transducer" of Claim 20. Benett et al. teach an ultrasound energy transducer on an analogous catheter (See Benett et al., Column 2, Lines 12-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an ultrasound transducer as taught by Benett et al. on the catheter

disclosed by Fogarty in order to more completely and effectively treat vascular blockage.

- b. In regard to Claim 71, Fogarty discloses “[A] therapeutic probe comprising: a proximal end portion, a distal end portion, a longitudinal portion located between the proximal and distal end portions” (See Fogarty, Figure 1). Fogarty also discloses a plurality of therapeutic agent delivering means (See Fogarty, Figure 8, Reference 38; See also Column 1, Lines 62-66). Fogarty does not explicitly meet the limitations wherein the therapeutic agent delivering means comprises an “ultrasound-delivering means provided in the longitudinal portion” or “wherein the ultrasound-delivering means comprises a plurality of ultrasound transducers”. Benett et al. teach an ultrasound energy transducer on an analogous catheter (See Benett et al., Figure 3; See also Column 1, Lines 13-17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide ultrasound transducers as taught by Benett et al. at the plurality of locations of therapeutic agent delivering means disclosed by Fogarty in order to more completely and effectively treat vascular blockage.
- c. In regard to Claim 75, Fogarty further discloses “wherein the front side surface comprises a helical shape” (See Fogarty, Figures 1 and 8; See also Column 1, Lines 9-11).

Conclusion

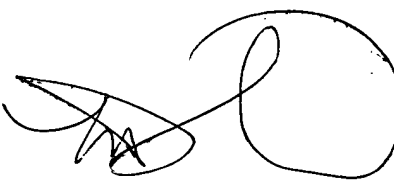
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Straightiff whose telephone number is (571) 272-4774. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MPS


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